

(iii) *Limitations.* For use in suckling beef calves (at least 45 days of age) up to 400 pounds (lb) of body weight. For subcutaneous ear implantation, one dose per animal. Do not use in bull calves intended for reproduction. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Steers*—(i) *Amount*—(A) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 mg progesterone and 2.5 mg estradiol benzoate) per implant dose.

(B) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of 9 pellets, each of 8 pellets containing 25 mg progesterone and 2.5 mg estradiol benzoate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* For animals weighing 400 lb or more; for subcutaneous ear implantation, one dose per animal. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* Reimplant 200 mg progesterone and 20 mg estradiol benzoate on approximately day 70 following an initial implant of 100 mg progesterone and 10 mg estradiol benzoate or 200 mg progesterone and 20 mg estradiol benzoate.

(ii) *Indications for use.* For additional improvement in rate of weight gain.

(iii) *Limitations.* For subcutaneous ear implantation. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 70055, Dec. 2, 2004]

§ 522.1962 Promazine hydrochloride.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) promazine hydrochloride.

(b) *Sponsor.* In § 510.600(c) of this chapter, see No. 000008 for conditions of use as in paragraph (c)(1)(i) of this section; see No. 000856 for conditions of use as in paragraph (c)(1)(ii) of this section; see No. 061623 for conditions of use as in paragraph (c)(1)(iii) of this section.

(c) *Conditions of use*—(1) *Amounts and indications for use.* (i) To horses either intramuscularly or intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, and to dogs and cats 1 to 3 milligrams per pound of body weight, every 4 to 6 hours as a tranquilizer or preanesthetic.

(ii) To horses either intramuscularly or intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, and to dogs and cats at 1 to 2 milligrams per pound of body weight, every 4 to 6 hours as a tranquilizer, preanesthetic, for minor operative procedures in conjunction with local anesthesia, as adjunctive therapy for tetanus, and as an antiemetic in dogs and cats prior to worming, or to prevent motion sickness in dogs.¹

(iii) To horses intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, as a tranquilizer and preanesthetic, as required.

(2) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18962, Mar. 27, 1981, as amended at 68 FR 59881, Oct. 20, 2003]

§ 522.2002 Propiopromazine hydrochloride injection.

(a) *Chemical name.* 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.

(b) *Specifications.* Propiopromazine hydrochloride injection contains 5 or 10 milligrams of the drug in each milliliter of sterile aqueous solution.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is administered either intravenously or intramuscularly to dogs and cats for tranquilization at a dosage level of

0.05–0.5 milligram per pound of body weight and is also administered intravenously to dogs and cats as a preanesthetic at a dosage level of 0.25 milligram per pound of body weight.

(2) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 60570, Dec. 11, 1981; 61 FR 5507, Feb. 13, 1996]

§ 522.2005 Propofol injection.

(a) *Specifications.* The drug is a sterile, nonpyrogenic, oil-in-water emulsion containing 10 milligrams of propofol per milliliter.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use as in paragraphs (c)(1) and (c)(2) of this section. See No. 000074 in § 510.600(c) of this chapter for use as in paragraph (c)(1) of this section.

(c) *Conditions of use—(1) Dogs.* (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for procedures lasting up to 5 minutes; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 5.5 to 7.0 milligrams per kilogram (2.5 to 3.2 milligrams per pound); for the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 3.3 milligrams per kilogram (0.5 to 1.5 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements.

(iii) Adequate data concerning safe use of propofol in pregnant and breeding dogs have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats.* (i) The drug is indicated for use as an anesthetic as follows: As a

single injection to provide general anesthesia for short procedures, for induction and maintenance of general anesthesia using incremental doses to effect, and for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 8.0 to 13.2 milligrams per kilogram (3.6 to 6.0 milligrams per pound). For the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 4.4 milligrams per kilogram (0.5 to 2.0 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements.

(iii) Adequate data concerning safe use of propofol in pregnant and breeding cats have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 66582, Dec. 18, 1996, as amended at 62 FR 61625, Nov. 19, 1997; 63 FR 24420, May 4, 1998; 64 FR 13510, Mar. 19, 1999]

§ 522.2012 Prostalene solution.

(a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of prostalene.

(b) *Sponsor.* No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use—Horses.* (1) It is used in mares for the control of estrus.

(2) It is administered at a dose of 5 micrograms per kilogram of body weight as a single subcutaneous injection.

(3) Not for use in horses intended for food.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[41 FR 26854, June 30, 1976, as amended at 61 FR 5507, Feb. 13, 1996]

§ 522.2063 Pyrilamine maleate injection.

(a) *Specifications.* The drug is a sterile aqueous solution with each milliliter containing 20 milligrams of pyrilamine maleate.

(b) *Sponsors.* See No. 000061 in § 510.600(c) of this chapter for uses in paragraph (c)(2)(i) of this section; see